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| 10/539,562 | 06/17/2005 | Kristopher Buchanan | 09138.0070 | 2677 |
| 63432 7590 02/04/2008 DAKO/FINNEGAN, HENDERSON, LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | | |
| EXAMINER | | | | |
| BOWERS, NATHAN ANDREW | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1797 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,562

Applicant(s)

BUCHANAN ET AL.

Examiner

NATHAN A. BOWERS

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47, 75 and 90-113 is/are pending in the application.
- 4a) Of the above claim(s) 1-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75 and 90-113 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 102306, 061705
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III, claims 75 and 90-113 in the reply filed on 12 December 2007 is acknowledged.

Claims 1-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12 December 2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 1) Claims 75 and 90-101 are rejected under 35 U.S.C. 102(b) as being anticipated by Richards (US 6296809).

With respect to claim 75, Richards discloses an automated sample processing system for processing a plurality of samples each on a respective carrier according to a processing protocol. Specifically, Richards indicates that samples are positioned on slides, which are in turn positioned on a carrier retention device in the form of a carousel (Figure 4:28). This is disclosed in column 6, lines 12-43. Column 6, lines 44-65

teaches that an active temperature regulation element comprising a resistive heaters, temperature sensors and a microprocessor controller is also provided to monitor the temperature of each sample slide during processing. Figure 9 indicates that each slide (37) is positioned just above a heating element (64) and a temperature sensor (68). This is further described in column 9, lines 4-66.

With respect to claims 90-95, Richards discloses the system in claim 75 wherein the processing system is capable of executing a variety of different techniques. Column 1, lines 18-47 and column 4, lines 5-15 state that the system can operate as either an automated immunohistochemistry processing system or a fluorescent in-situ hybridization processing system. Column 3, lines 29-40 state that the apparatus is designed to accommodate DNA probe and/or antibody based staining procedures.

With respect to claims 96-98, Richards discloses the system in claim 95 wherein an active temperature reduction element is additionally provided. In column 7, lines 1-10 and column 14, lines 51-62, Richards teaches that cooling of the slide is accomplished through the use of Peltier coolers and fans.

With respect to claims 99-101, Richards discloses the system in claim 95 wherein the active temperature regulation element comprises a temperature ramp up and ramp down element, thus inducing regulated temperature increases and decreases within the sample. This is described in column 6, lines 44-65, column 9, lines 4-66, column 18, line 57 to column 19, line 28, and generally throughout the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- 2) Claims 102-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richards (US 6296809) in view of Ammann (US 20050233370).

With respect to claims 102-108, Richards discloses the system set forth in the rejections above. Richards discloses at least one container having a reagent therein, as well as a sample carrier retention device. Sample temperature control elements are provided for regulating the temperature of the contents of the sample carrier retention device. Richards, however, does not expressly disclose that reagent temperature control elements are provided for regulating the temperature of reagents before they are applied to the sample.

Ammann discloses an automated system for processing a plurality of reaction receptacles each capable of holding and transporting a sample. Reaction receptacles are transported to an arrangement of incubators (Figure 4:600,602,604,606) where they are maintained at a predetermined temperature. Paragraphs [0130], [0332] and [0337]-[0369] state that reagents are stored in separate containers located within a reagent cooling bay (Figures 35-39). Ammann teaches that thermoelectric modules and fan units provide the desired cooling capacity, and are capable of regulating the temperature of a plurality of reagents maintained in a plurality of containers.

Richards and Ammann are analogous art because they are from the same field of endeavor regarding automated sample processing systems.

At the time of the invention, it would have been obvious to equip Richard's reagent storage containers with cooling elements and a control system capable of regulating the temperature within the reagent storage containers. Reagents typical of microarray processing systems are known in the art to be temperature sensitive and susceptible to degradation if maintained under undesirable conditions. As evidenced by

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Ammann, it is well known in the art to keep reagents at cool temperatures during storage to ensure that they do not prematurely expire.

With respect to claims 109-113, Richards and Ammann disclose the apparatus set forth in claim 102 as set forth in the 35 U.S.C. 103 rejections above. In addition, Richards clearly indicates that a sample temperature control element is provided to ramp up and ramp down the temperature of the sample maintained within the carousel retention device during processing. This has been described in the rejections above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Bogan (US 6541261) and Rodgers (US 6403036) references teach the state of the art regarding automated temperature regulation elements for controlling the temperature of a sample. The Malterer (US 20030215357) reference teaches the state of the art regarding automated temperature regulation elements for controlling the temperature of a reagent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GLADYS JP CORCORAN/
Supervisory Patent Examiner
Art Unit 1797

NAB